APR 1 1 2014

5.0 Traditional 510(k) Summary
Disposable Concentric Stimulation Probe

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR § 807.92(a).

807.92(a)(1) **Submitter Information:**	Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 FDA Registration #: 1067162 Owner Operator #: 9052354
Official Correspondent:	Daniel McCoy Director of Engineering and Regulatory Affairs Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 ext. 102 Email: dmccoy@rhythmlink.com
Summary Date:	March 6, 2014
807.92(a)(2) **Device Identification:**	**Proprietary Device Name:** Disposable Concentric Stimulating Probe (Trade name has not been finalized at this time) **Generic Device Name:** Surgical Nerve Stimulator/Locator **Regulatory Class:** Class II **Classification Name:** 21 CFR §874.1820, Surgical Nerve Stimulator/Locator **Product Code:** ETN
807.92(a)(3) **Predicate Device(s):**	**K103128** Cadwell Disposable Stimulator Probes
807.92 (a)(4)	The Disposable Concentric Stimulating Probe is intended to be used to reach

Device Description:	target nerves and to locally stimulate them in order to provide a measurable response. The stimulus will have a very small current spread to reduce the innervation of the surrounding nerves. The concentric design has two main parts, an inner stainless steel wire and an outer cannula also insulated from reading un-intended signals. The Inner wire is isolated from the outer stainless steel cannula using a biocompatible heat shrink tubing. This Inner Wire acts as the stimulator and is surrounded by the outer cannula. The Outer Cannula is isolated with a biocompatible heat shrink which isolates the outer cannula allowing contact in a localized area of the intended nerves of interest. The inner wire, the cathode, is stimulated using EMG/EP electroneurodiagnostic equipment cleared for the stimulation of nerve tissue and recording muscle activity during surgical procedures (not part of this 510(k) submission) The outer cannula acts as the anode or reference. The Inner wire and outer cannula are isolated from each other using a dielectric heat shrink and are connected to a color coded pair of leadwires which are terminated by two DIN 42 802 touch proof connectors. The concentric stimulators are terminated on the distal end inside of a plastic handle and are independently connected to the leadwires.
807.92(a)(5) **Intended Use(s)**	The Rhythmlink Disposable Concentric Stimulating Probe is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerve and spinal nerve roots during surgery. The Rhythmlink Disposable Concentric Stimulating Probe is a single patient use device.

807.92(a)(6) Technological Characteristics

An evaluation of the technological characteristics of the Rhythmlink Disposable Concentric Stimulating Probe where compared to the predicate device, Cadwell Probes.

	Rhythmlink Concentric Probe	**Predicate Device Cadwell**
510(k) Number	K132138	K103128
Shaft Length	80 – 330mm	80 – 340mm
Handle Length	100mm	110mm
Leadwire Length	1.0m – 3.0m	2.0m
Tip Diameter/Exposure	Ø1.6mm x 0.0 – 0.3mm	Ø1.3mm x 0-0.3mm
Shaft Material	SST 316 and SST 304	SST 316
Shaft Insulation	PET	PTFE
Handle Material	Medical Grade ABS	Medical Grade ABS
Lead Wire Material	Tin Plated Copper	Tin Plated Copper
Lead Wire Insulation	Medical Grade PVC	Medical Grade PVC

807.92(b)(1) Summary of Non-Clinical Tests

Non-clinical bench testing was comprised of dimensional measurements and performance tests. Dimensional testing was conducted of the Probe diameter and Probe lengths. Performance testing was conducted and analyzed for a continuity of .5 Ohms, Hi Pot testing of insulator breakdown, stimulation delivery, Pull-off strength and leadwire (patient cables) strength. The device was sterilized under the current, validated EO Sterilization Cycle 93007, and testing for residual EtO and ECH levels determined that the residuals are at the lowest possible limits.

Biocompatibility per ISO-10993-1: 1997, Part I "Biological Evaluation of Medical Devices, Evaluation and Testing" was confirmed by analyzing biocompatibility tests on the device (exclusive of the handle and lead wire). The biocompatibility testing is summarized in the table below:

Test	Results	Conclusion
ISO BET Get Clot Testing	The system did not interfere with the lysate reaction, and no inhibition or enhancement or enhancement was present. The test articles did not clot at the neat concentration. The geometric mean endpoint concentration of each test article was <0.06 EU/mL and each contained <0.9 EU/Device of bacterial endotoxin. The results are acceptable.	The device is non-pyrogenic.

	USP Inhibition and Enhancement Testing, Gel Clot Method	The test Concentric Stimulation Probe does not inhibit or enhance the Bacterial Endotoxin Test according to the USP guidelines.	The device is non-pyrogenic.
	ISO MEM Elution Test	There was no biological reactivity (Grade 0) of the cells exposed to the test article extract. The response obtained from the positive and negative control article extracts confirmed the suitability of the test system.	The device is non-cytotoxic.
	ISO Intracutaneous Reactivity Test	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.	The device is non-irritant.
	Once the verification testing was completed it was confirmed that the proposed Rhythmlink Concentric Stimulation Probes are as safe and effective as the predicate device.		
807.92(b)(2) Clinical Tests **807.92(b)(3) Clinical Summary**	There was no clinical testing performed on the proposed device.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

Rhythmlink International, LLC
Mr. Daniel E. McCoy
Director of Engineering and Regulatory Affairs
1140 First Street South
Columbia, South Carolina 29209

Re: K132138
Trade/Device Name: Rhythmlink disposable concentric stimulating probe
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical Nerve Locator
Regulatory Class: Class II
Product Code: PDQ, ETN
Dated: March 1, 2014
Received: March 14, 2014

Dear Mr. McCoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132138

Device Name
Disposable Concentric Stimulating Probe

Indications for Use *(Describe)*
The Rhythmlink Disposable Concentric Stimulating Probe is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerve and spinal nerve roots during surgery.
The Rhythmlink Disposable Concentric Stimulating Probe is a single patient use device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.11 13:51:09 -04'00'

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